

K103745

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## 5. 510(k) Summary

### 1. SUBMITTER INFORMATION

Name: GlaxoSmithKline Consumer Healthcare  
Address: 1500 Littleton Road  
Parsippany, NJ 07054-3884  
Contact Person: Wendy A. McManus  
Telephone/Fax: 973-889-4415  
973-889-2501 (fax)  
Date Summary Prepared: December 21, 2010

### 2. DEVICE NAME

Device Name: Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief  
Trade or Proprietary Name: Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief  
Common or Usual Name: Saliva, Artificial  
Classification Name (if known): Saliva, Artificial

### 3. IDENTIFICATION OF EQUIVALENCE

Laclede, Inc. *Oral Balance Gel* cleared in (K061331)  
Laclede, Inc. *Oral Balance Liquid* cleared in (K061331)

### 4. DEVICE DESCRIPTION

Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief is a specially formulated artificial saliva substitute which contains moisturizers, humectants, a protein, and patented salivary enzymes that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of

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Dry Mouth. The spray is supplied in a 1.5 oz. non-pressurized pump action spray bottle fitted with cap.

#### 5. STATEMENT OF INTENDED USE

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

*Indication for Use:* Relieves the symptoms of dry mouth; refreshes, moisturizes, soothes oral irritation, and lubricates oral dryness.

#### 6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Characteristics of the device compared to the predicate devices.  
Substantial Equivalence Comparison Chart

<b>PRODUCT:</b>	<b><i>Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief (Proposed Device)</i></b>	<b><i>Biotène Oral Balance Gel (Predicate 1)</i></b>	<b><i>Biotène Oral Balance Liquid (Predicate 2)</i></b>
<b>INTENDED USE</b>	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia
<b>METHOD OF USE</b>	Ready to use spray	Ready to use gel	Ready to use liquid
<b>APPLICATIONS PER DAY</b>	As needed	As needed	As needed
<b>DISEASE STATE</b>	Xerostomia	Xerostomia	Xerostomia
<b>AREA OF USE</b>	Oral Cavity	Oral Cavity	Oral Cavity
<b>TYPE OF PRODUCT</b>	Liquid	Gel	Liquid
<b>PRESENTATION</b>	Non-sterile	Non-sterile	Non-sterile

#### 7. Discussion and conclusions from the nonclinical and clinical tests

Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief has been shown in nonclinical studies to be safe (Toxicology Assessment) and stable (Stability Study) for its intended use. It has also been shown to be effective (Use Study).



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Ms. Wendy A. McManus  
Regulatory Associate, US Regulatory Affairs  
Glaxosmithkline Consumer Healthcare (GSKCH)  
1500 Littleton Road  
Parsippany, New Jersey 07054

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Re: K103745  
Trade/Device Name: Biotene Moisturizing Mouth Spray for Dry Mouth Symptom Relief  
Regulation Number: None  
Regulation Name: Cavity Varnish  
Regulatory Class: Unclassified  
Product Code: LFD  
Dated: May 24, 2011  
Received: June 1, 2011

Dear Ms. McManus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

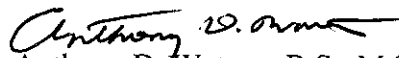
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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#### 4. Indications for Use Statement

**510(k) Number (if known):** N/A

**Device Name:** Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief

**Indications for Use:**

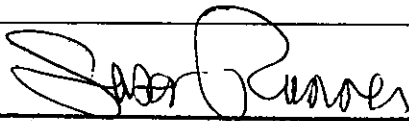
Relieves the symptoms of dry mouth; refreshes, moisturizes, soothes oral irritation, and lubricates oral dryness.

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Officers of Device Evaluation (ODE)**

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use X \_\_\_\_\_

(Per 21 CFR 801.109)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:

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